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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,334	08/06/2001	Tian Xu	6523-020-999	5438

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Pennie & Edmonds
1155 Avenue of the Americas
New York, NY 10036-2711

EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	5

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,334	Applicant(s) Xu et al.
	Examiner Shin-Lin Chen	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-113* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a recombinant non-human animal with inactivated lats gene.

Group II, claim(s) 6-12, 14-22 and 37, drawn to a method for screening a compound that is a protein for activity in treating or preventing **cancer** comprising administering the compound to the recombinant non-human animal.

Group III, claim(s) 6-12, 14-22 and 37, drawn to a method for screening a compound that is an antibody for activity in treating or preventing **cancer** comprising administering the compound to the recombinant non-human animal.

Group IV, claim(s) 6-23 and 37, drawn to a method for screening a compound that is a nucleic acid for activity in treating or preventing **cancer** comprising **recombinantly expressing** the compound in the recombinant non-human animal.

Group V, claim(s) 24-35 and 37, drawn to a method for screening a compound that is a protein for activity in treating or preventing a **disease or disorder associated with pituitary**

dysfunction, such as LH hypogonadotropic hypogonadism, comprising administering the compound to a lats knockout animal.

Group VI, claim(s) 24-35 and 37, drawn to a method for screening a compound that is an antibody for activity in treating or preventing a **disease or disorder associated with pituitary dysfunction**, such as LH hypogonadotropic hypogonadism, comprising administering the compound to a lats knockout animal.

Group VII, claim(s) 24-37, drawn to a method for screening a compound that is a nucleic acid for activity in treating or preventing **a disease or disorder associated with pituitary dysfunction**, such as LH hypogonadotropic hypogonadism, comprising **recombinantly expressing** the compound in the recombinant non-human animal.

Group VIII, claim(s) 38-59, drawn to a method for treating a cancer by administering to a subject **a protein**, such as lats protein, that promote lats function.

Group IX, claim(s) 60-66, drawn to a method for treating a cancer by administering to a subject **a nucleic acid** encoding a lats protein.

Group X, claim(s) 67-81, 89-92 and 100, drawn to a purified complex of lats and cdc2 protein, a kit comprising a lats protein, a lats derivatives, a lats analog, or a complex of a lats and a cdc2 protein, and a pharmaceutical composition comprising the complex of lats and dcd2 protein.

Group XI, claim(s) 82, 83, 93 and 100, drawn to an antibody that binds to the complex of lats and cdc2 protein, a kit comprising said antibody, and a pharmaceutical composition comprising said antibody.

Group XII, claim(s) 67, 84-88, 94-98 and 100, drawn to an isolated nucleic acid comprising a nucleotide sequence encoding a lats protein and a nucleotide sequence encoding a cdc2 protein, a host cell comprising said nucleic acid, a pharmaceutical composition comprising said nucleic acid, a method of producing protein by using said host cell, and a kit comprising said nucleic acid.

Group XIII, claim(s) 99, drawn to a method of diagnosing or screening for the presence of a predisposition for developing a disease or disorder characterized by an aberrant level of a complex of a lats protein and a cdc2 protein in a subject by measuring the **protein level** of said complex.

Group XIV, claim(s) 99, drawn to a method of diagnosing or screening for the presence of a predisposition for developing a disease or disorder characterized by an aberrant level of a complex of a lats protein and a cdc2 protein in a subject by measuring the level of **RNA** encoding the lats and cdc2 proteins.

Group XV, claim(s) 99, drawn to a method of diagnosing or screening for the presence of a predisposition for developing a disease or disorder characterized by an aberrant level of a complex of a lats protein and a cdc2 protein in a subject by measuring **functional activity** of said complex.

Group XVI, claim(s) 101 and 102, drawn to a method for modulating the activity of cdc2 comprising administering a molecule that promotes lats function.

Group XVII, claim(s) 101 and 103, drawn to a method for modulating the activity of cdc2 comprising administering a molecule that inhibits or antagonizes lats function.

Group XVIII, claim(s) 104 and 105, drawn to a method for treating or preventing a disease or disorder associated with an aberrantly high level of cdc2 in a subject by using **a lats protein**, a lats derivatives or analog that promotes lats function.

Group XIX, claim(s) 104 and 105, drawn to a method for treating or preventing a disease or disorder associated with an aberrantly high level of cdc2 in a subject by using **a nucleic acid** encoding a lats protein, a lats derivatives or analog that promotes lats function.

Group XX, claim(s) 104 and 105, drawn to a method for treating or preventing a disease or disorder associated with an aberrantly high level of cdc2 in a subject by using **a lats agonist** that is an organic compound other than protein and nucleic acid.

Group XXI, claim(s) 106 and 107, drawn to a method for treating or preventing a disease or disorder associated with an aberrantly low level of cdc2 in a subject by using **a lats derivatives or analog that inhibits or antagonizes lats function**.

Group XXII, claim(s) 106 and 107, drawn to a method for treating or preventing a disease or disorder associated with an aberrantly low level of cdc2 in a subject by using an **anti-lats antibody**.

Group XXIII, claim(s) 106 and 107, drawn to a method for treating or preventing a disease or disorder associated with an aberrantly low level of cdc2 in a subject by using a **lats antisense nucleic acid**.

Group XXIV, claims(s) 108 and 109, drawn to a method for screening a molecule for efficacy in treating or preventing a cancer by contacting the cancer cells with said molecule and comparing the proliferation or survival of the contacted cells.

Group XXV, claims(s) 110, drawn to a method for screening a molecule for activity to modulate cdc2 levels or activity comprising contacting cells with said molecule and comparing the level of cdc2 **protein** in cells.

Group XXVI, claims(s) 110, drawn to a method for screening a molecule for activity to modulate cdc2 levels or activity comprising contacting cells with said molecule and comparing the level of cdc2 **mRNA** in cells.

Group XXVII, claims(s) 110, drawn to a method for screening a molecule for activity to modulate cdc2 levels or activity comprising contacting cells with said molecule and comparing the **activity** of cdc2 protein in cells.

Group XXVIII, claims(s) 111 and 112, drawn to a method for screening a molecule for activity to **inhibit** the formation of a complex of lats and cdc2 protein comprising measuring the levels of said complex formed from lats and cdc2 proteins with or without the presence of said molecule.

Group XXIX, claims(s) 111 and 113, drawn to a method for screening a molecule for activity to **promote** the formation of a complex of lats and cdc2 protein comprising measuring the levels of said complex formed from lats and cdc2 proteins with or without the presence of said molecule.

2. The inventions listed as Groups I-XXIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature that could be shared by groups I-XXIX is the mammalian lats gene or protein encoded by said gene. Tao et al., 1996, teaches a mouse lats gene sequence, Geneseq Accession No. AAT42119, that is 99.9% identical to SEQ ID No. 3 and teaches a human lats gene sequence, Geneseq Accession No. AAT 42118, that is 100% identical to SEQ ID No. 1 of the present invention. Thus, the present invention does not contribute any common special technical feature over the prior art.

Groups II-IV are directed to materially different methods using compositions that differ in chemical structures, physical properties, and biological functions: proteins, nucleic acids and antibodies. Those method differ at least in process steps, reagents and dosages used, schedules used, response variables, and criteria for success. Therefore, they do not relate to a single general inventive concept under PCT Rule 13.1. Similarly, groups V-VII, VIII-IX, X-XII and XXI-XXIII do not relate to a single general inventive concept under PCT Rule 13.1.

Groups XIII-XV are directed to materially different methods that measure protein levels, such as by using antibody, measure mRNA level, such as by using nucleic acid, or measure functional activity of a complex. Those method differ at least in process steps, reagents and dosages used, schedules used, response variables, and criteria for success. Therefore, they do not relate to a single general inventive concept under PCT Rule 13.1. Similarly, groups XXV-XXVII do not relate to a single general inventive concept under PCT Rule 13.1.

Groups XVI-XVII are directed to materially different methods that differ at least in objectives, process steps, reagents and dosages used, schedules used, response variables, and criteria for success: using a molecule that promote lats function vs using a molecule that inhibits or antagonizes lats function. Similarly, groups XXVIII-XXIX are directed to materially different methods that differ at least in objectives, process steps, reagents and dosages used, schedules used, response variables, and criteria for success: using a molecule that inhibits formation of a complex of lats and cdc2 protein vs using a molecule that promotes formation of a complex of lats and cdc2 protein. Thus, they do not relate to a single general inventive concept under PCT Rule 13.1.

Groups XVIII-XX are directed to materially different methods using compositions that differ in chemical structures, physical properties, and biological functions: proteins, nucleic acids and lats agonists. Those method differ at least in process steps, reagents and dosages used, schedules used, response variables, and criteria for success. Therefore, they do not relate to a single general inventive concept under PCT Rule 13.1.

Group I and X-XII are drawn to different products that differ in chemical structures, physical properties, and biological functions: transgenic animals, proteins, nucleic acids and antibodies. They are different products having different usages and the present invention does not contribute common special technical feature over the prior art. Therefore, they do not relate to a single general inventive concept under PCT Rule 13.1.

Groups II-IV, V-VII, VIII-IX, X-XII, XIII-XV, XVI-XVII, XVIII-XX, XXI-XXIII, XXIV, XXV-XXVII and XXVIII-XIX are drawn to methods that differ at least in objectives, process steps, reagents and dosages used, schedules used, response variables, and criteria for success. A method for screening a compound for treating or preventing cancer is different from a method for screening a compound for treating or preventing a disease or disorder associated with pituitary dysfunction because a cancer and a disease or disorder associated with pituitary dysfunction are two very different diseases. A method for treating a cancer is very different from a method for screening a compound because they have different objectives and differ in process steps, reagents and dosages used, schedules used, response variables, and criteria for success. Similarly, a method for treating a cancer is different from a method of treating or preventing a disease or disorder associated with an aberrantly high or aberrant low level of cdc2. Thus, they do not relate to a single general inventive concept under PCT Rule 13.1.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.